Remarks

The Office Action mailed February 27, 2004 has been received and reviewed. Claims 2, 3, 10, 11, 18 and 20 having been amended; claims 1, 2, 7-9, 12, 13, 15, 16, 22, 24-35 and 37 having been canceled, without prejudice; and claim 38 having been added, the pending claims are claims 3-6, 10, 11, 14, 17-21, 23, 36 and 38. Reconsideration and withdrawal of the rejections are respectfully requested.

The amendment to claim 3 reciting an antigenic portion of the i-antigen polypeptide comprising amino acids 21-452 of SEQ ID NO:7 is supported by the specification at, for example, page 52, lines 15-17. The amendment to claim 4 reciting a terminal membrane targeting portion encoded by SEQ ID NO:19 or SEQ ID NO:20 is supported by the specification at, for example, page 12, lines 26-31. The amendment to claims 10 and 11 reciting a nucleic acid molecule comprising at least 50 nucleotides is supported by the specification at, for example, page 17, lines 27-28. New claim 38 directed to a complementary nucleic acid molecule is supported by the specification at, for example, page 16, line 30 to page 17, line 2.

Allowance of Claims

Applicant acknowledges, with appreciation, the allowance of claims 5 and 36.

Rejection under 35 U.S.C. §112, First Paragraph

The Examiner has maintained the rejection of claims 3-4, 6, 10-11, 14, 17-21, and 23 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner indicated the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

The Examiner maintains the assertion that the specification does not provide an adequate description of the genus of nucleic acid molecules that encode "an antigenic portion of an i-antigen polypeptide having amino acid sequence SEQ ID NO:7" (claim 3) and "a terminal

membrane targeting portion of an i-antigen polypeptide having amino acid sequence SEQ ID NO:7" (claim 4). Applicants disagree; however, in order to advance prosecution of the above-identified application, claims 3 and 4 have been amended as follows.

Claim 3 has been amended to recite that the *antigenic portion* of the i-antigen polypeptide having amino acid sequence SEQ ID NO:7 *comprises amino acids 21-452 of SEQ ID NO:7.* The "antigenic portion" recited in claim 3, as amended, is thus an internal subsequence of SEQ ID NO:7.

Claim 4 has been amended to recite that the *terminal membrane targeting portion* of SEQ ID NO:7 is *encoded by SEQ ID NO:19 or SEQ ID NO:20.* Note that SEQ ID NO:19 is a 60 nucleotide sequence that encodes the N-terminal 20 amino acids of SEQ ID NO:7, and SEQ ID NO:20 is a 60 nucleotide sequence that encodes the C-terminal 20 amino acids of SEQ ID NO:7. The "terminal membrane targeting portion" recited in claim 4, as amended, is thus a terminal subsequence of SEQ ID NO:7.

Claim 3, as amended, now recites an antigenic portion of an i-antigen polypeptide comprising an internal amino acid sequence, amino acids 21-452, of SEQ ID NO:7. Example 5 (specification at page 51, line 15 to page 53, line 10) describes the synthesis of full-length and truncated (i.e., missing amino acids 1-20, or missing amino acids 453-468) 55kD i-antigen nucleic acid vectors. Specifically, vectors encoding the full length 55kD i-antigen sequences (SEQ ID NO:102 and SEQ ID NO:53, which is a point mutation compared to SEQ ID NO:5) are described. In addition, two different truncated 55kD i-antigen nucleotide sequences are described, the first lacking the coding region for the signal peptide at the N-terminus (residues 1-20), and the second lacking the hydrophobic stretch at the extreme C-terminus of the protein (amino acids 453-468) (specification at page 52, lines 14-17).

All of these 55kD-related constructs *(full length as well as N– or C- terminus truncated)* were shown to be *immunogenic* in fish in Example 7 (specification at pages 54-57). It is thus respectfully submitted that the Examiner erred in asserting that the specification's only working example of an antigenic portion is "a single 'fragment' of the 48kD antigen in which 19 amino

acids at the Carboxy terminus are deleted." Further, it is submitted that claim 3, as amended, and claims dependent therefrom, find sufficient written description in the specification.

Claim 4, as amended, now recites a terminal membrane targeting portion of SEQ ID NO:7 encoded by SEQ ID NO:19 or SEQ ID NO:20. As described in the specification at page 12, lines 26-31, and shown in Fig. 2(a), SEQ ID NO:19 contains nucleotides 1 through 60 of SEQ ID NO:3; and SEQ ID NO:20 contains nucleotides 1345 through 1404 of SEQ ID NO:3. As a reminder, SEQ ID NO:3 encodes the full length 55 kD i-antigen polypeptide, SEQ ID NO:7. The terminal membrane targeting portions recited in claim 4 represent the first (amino acids 1-20) or last (amino acids 449-458) 20 amino acids of SEQ ID NO:7 (encoding the full length 55 kD i-antigen). It is thus respectfully submitted that the specification provides sufficient written description for claim 4, as amended, and those dependent therefrom.

In view of the amendments to claims 3 and 4, reconsideration and withdrawal of the rejection of claims 3, 4, 6, 10, 11, 14, 17-21 and 23 under 35 U.S.C. §112, first paragraph, is respectfully submitted.

Rejection under 35 U.S.C. §102(b)

The Examiner has maintained the rejection of claims 4, 6, 14, 17, 19 and 21 under 35 U.S.C. §102(b) as being anticipated by Clark et al. This rejection is respectfully traversed.

For reasons described above in connection with the rejection under 35 U.S.C. §112, first paragraph, claim 4 has been amended to *delete* recitation of a terminal membrane portion of an i-antigen polypeptide having amino acid sequence SEQ ID NO:7, which terminal membrane targeting portion *comprises at least about 10 amino acids*, and now recites that the terminal membrane targeting portion is *encoded by SEQ ID NO:19 or SEQ ID NO:20*. The amino acid sequences encoded by SEQ ID NOs: 19 and 20 (namely the first and last 20 amino acids of SEQ ID NO:7) are not taught in Clark et al. Clark et al. therefore does not anticipate claim 4 or claims dependent therefrom. Reconsideration and withdrawal of the rejection of claims 4, 6, 14, 17, 19 and 21 under 35 U.S.C. §102(b) as being anticipated by Clark et al. is accordingly requested.

The Examiner newly rejected claim 10 as being anticipated by Birkett et al. (U.S. Patent 5,302,527), which discloses isolated random hexamer nucleic acids contained within a multiprime kit. This rejection is respectfully traversed.

Claim 10 has been amended to recite that the nucleic molecule that hybridizes to the recited sequences *comprises at least 50 nucleotides*. A similar amendment was made to claim 11 in view of the deletion of the recitation of an antigenic portion of an i-antigen protein. Reconsideration and withdrawal of the rejection of claim 10 under 35 U.S.C. §102(b) as being anticipated by Birkett et al. is accordingly requested.

Summary

It is respectfully submitted that the pending claims 3-6, 10, 11, 14, 17-21, 23, 36 and 38 are in condition for allowance, and notification to that effect is respectfully requested.

The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper is being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 13 day of July 2004, at 3:10pm (Central Time).

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July 13, 2004

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